Radiological Health (the Intercenter Agreements).

Concerning the implementation of the final rule for these combination products, the FDA stated that natural rubber combination products that are listed in the Intercenter Agreements as being regulated under device labeling provisions will be required to comply with the final rule on the effective date. FDA stated that natural rubber combination products that are listed in the Intercenter Agreements as being regulated under drug or biologic labeling provisions will be subject to the labeling requirements on September 30, 1998, or when FDA amends the Intercenter Agreements to provide that these types of combination products are subject to the requirements, whichever is later. FDA stated that it would provide notice in the **Federal Register** of the amendments to the Intercenter Agreements to apply the labeling requirements to all natural rubber combination products regulated under drug and biologic provisions. FDA also stated then that: ''the agency anticipates that the Drug/Device Intercenter Agreement will be amended to reflect that prefilled drug vial containers, transdermal patches, infusion pumps, and prefilled syringes that presently are regulated under drug authorities are also subject to this regulation'' (62 FR 51021 at 51026).

The agency has received numerous inquiries about, and objections to, the application of the natural rubber labeling requirements to combination drug/device products and to combination biologic/device products that currently are regulated under drug and biologic labeling provisions. These include a citizen petition submitted by the Health Industry Manufacturers Association (Docket No. 98P–0012/CP1). One concern was that some combination products may raise different labeling issues than single-entity device products. In addition, a concern was raised that adequate notice and opportunity for comment was not provided with regard to the applicability of the rule to combination products that currently are regulated under drug and biologic labeling provisions.

FDA believes that the notice provided was legally sufficient. However, upon consideration of these comments and the need to provide a uniform labeling approach for all drug and biological products, including combination products currently regulated under drug and biologic labeling provisions, FDA has decided that further opportunity for public comment should be provided on how natural rubber labeling requirements should be applied to all products regulated as drugs and biologics. FDA believes that it would benefit from additional public comment on whether there are labeling issues that are unique to products regulated as drugs and biologics as well as on whether the agency should adopt rules and guidance that would apply to all natural rubber-containing products regulated under the drug and biologic labeling provisions rather than only to combination products.

Therefore, FDA is announcing that it does not intend to amend the Intercenter Agreements as stated in the preamble to the final rule. Instead, FDA intends to initiate a proceeding to propose requirements for labeling statements on products regulated as drugs and biologics, including combination products currently regulated under drug and biologic labeling provisions, that contain natural rubber that contacts humans. Such a proceeding may include a combination of proposed rulemaking and guidance and will offer opportunity for public comment. In the interim, FDA is providing notice that it does not intend to apply to combination products regulated under human drug or biologic labeling provisions its September 30, 1997, final rule requiring certain labeling statements for all medical devices that contain or have packaging containing natural rubber that contacts humans.

Dated: April 30, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–11982 Filed 5–5–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OR–67–7282, OR–70–7285; FRL–5976–5]

Approval and Promulgation of State Implementation Plans: Oregon

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Pursuant to procedures described in the January 19, 1989 **Federal Register**, EPA recently approved two minor State Implementation Plan (SIP) revisions submitted by the Oregon Department of Environmental Quality (ODEQ). These revisions include: changes to the definition of Volatile Organic Compounds (VOC) in the Oregon Administrative Rules (OAR) consistent with changes made in the federal definition and delisting certain compounds no longer considered VOCs; and, changes in the OAR that increase Air Contaminant Discharge Permit Fees for stationary sources to recover costs of operating the state permit program. This document lists the revisions EPA has approved and incorporates the relevant material into the Code of Federal Regulations.

EFFECTIVE DATE: June 5, 1998.

ADDRESSES: Copies of Oregon's State SIP revision requests and EPA's letter notices of approval are available for public inspection during normal business hours at the following locations: EPA, Region 10, Office of Air Quality (OAQ–107), 1200 Sixth Avenue, Seattle, Washington 98101; State of Oregon Department of Environmental Quality, 811 SW Sixth Ave., Portland, OR 97204–1390.

FOR FURTHER INFORMATION CONTACT: Tracy Oliver, Office of Air Quality (OAQ–107), EPA, Seattle, Washington, (206) 553–1388.

SUPPLEMENTARY INFORMATION: EPA Region 10 has approved the following minor SIP revision requests under section 100(a) of the Clean Air Act (Act):

State	Subject matter	Date of submission	Date of approval
OR	Changes to the definition of VOC in the OAR consistent with changes in the federal definition. Delisting perchloroethylene, acetone, HFC 43–10mee and HCFC 225ca and cb which are no longer considered VOCs.	5–22–97	6–16–97
OR	Changes in the OAR that increase the Air Contaminate Permit Fees for stationary sources and allow the state to recover the costs of operating the permit program.	11–13–97	2–13–98

EPA has determined that each of these SIP revisions complies with all applicable requirements of the Act and EPA policy and regulations concerning such revisions. Due to the minor nature of these revisions, EPA concluded that conducting notice-and-comment rulemaking prior to approving the revisions would have been ''unnecessary and contrary to the public interest'' and hence not required by the Administrative Procedure Act, 5 U.S.C. 553(b). Each of these SIP approvals became final and effective on the date of EPA approval as listed in the chart above.

I. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D, of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 6, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the Implementation Plan for the State of Oregon was approved by the Director of the Office of Federal Register on July 1, 1982.

Dated: February 20, 1998.

Chuck Findley,

Acting Regional Administrator, Region X.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: U.S.C. 7401 et seq.

Subpart MM—Oregon

2. Section 52.1970 is amended by adding paragraph (c)(123) to read as follows:

§ 52.1970 Identification of plan.

* * * * *

(c) * * *

(123) On May 22, 1997, ODEQ submitted changes to the definition of Volatile Organic Compounds (VOC) in the Oregon Administrative Rules (OAR) consistent with changes made in the federal definition and delisted certain compounds no longer considered VOCs under the new definition. On November 13, 1997, ODEQ submitted changes in the OAR that increased Air Contaminant Discharge Permit Fees for stationary sources to recover costs of operating the state permit program.

(i) Incorporation by reference.

(A) Oregon Administrative Rules 340–022–0102(73) and 340–028–0110(129), effective May 9, 1997; Oregon Administrative Rule 340–028–1750, effective August 27, 1997.

[FR Doc. 98–11882 Filed 5–5–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300649; FRL–5787–9]

RIN 2070–AB78

Various Inert Ingredients; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance exemptions for residues of 2-